Improving Fixation of a Previously Designed Pediatric Tibial Stent

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Problem Statement

• Tibia fractures are common in children

• **Need for a surgically implanted device, which would provide more structural stability and aid in healing of the fracture.**

• A previous design team produced a working device, which is held in place by static friction against the canal wall.
  • not fully fixated against the walls of the bone canal, and the friction force of the device is not sufficient to prevent axial rotation within the canal.

• Previous semester’s work:
  • Designed pediatric tibial stent

• **This semester’s focus:**
  • Improving fixation of previous semester’s design
Background

- 5% of pediatric fractures occur at tibia\(^1\)
- Tibia is a load bearing bone
  - Correct alignment is essential
- Many bone fractures can be set with a cast or a splint; however, the tibia may require surgery followed by serial casting to repair the injury.
Background

- Differences in child and adult tibia
  - Epiphyseal growth plates at proximal and distal ends of bone
  - Involved in growth spurt during puberty

- Growth plates must be avoided in all surgical procedures for pediatric patients
  - May lead to growth complications and more surgery if disturbed
Current Devices: Rigid Intramedullary Device

Titanium rod

- Rod is rotationally fixed and is further stabilized by lateral screws installed at proximal and distal locations\(^8\)

- Inserted into the bone at the top passing through the epiphyseal growth plate
  - Cannot be used for pediatric patients
Current Devices: Elastic Nails

Made of titanium

2 elastic nails = six areas of contact meant to provide constant pressure and stabilization for fractured tibia\(^4\)

- Avoids growth plate
- Optimal function with mid-bone fracture
- No rotational fixation

- Diameter of elastic nails = 2.5 – 4 mm\(^5\)
400/402 Design Overview

- Center cable is galvanized steel; outer wires are stainless steel
- End cap and mid-cap
- Fixed at bottom with nail
- Converts tensile force into radial force which stabilizes fracture
- Increases points of contact compared to elastic nails
Product Design Specifications

- **Function**
  - Improve fixation by limiting axial rotation

- **Design Requirements**
  - **Performance**
    - Flexible to enter bone (45° angle)
    - Rigid to stabilize fracture
    - Can be removed after 2-9 months
  - **Size**
    - Match dimensions of previous semester’s design
  - **Safety**
    - Biocompatible
      - Surgical grade metals
    - Easily sterilized
  - **Standards and Specifications**
    - FDA guidelines for implants
Design Alternative 1: Mesh Cylinder

- Based on arterial stent
- Weave stainless steel wires through mesh to hold in place and prevent buckling
- When device is expanded, mesh also expands
- Provides increased surface contact with interior of medullary canal
Design Alternative 2: 2-sided Umbrella

- Based on folding umbrella design
- Rigid wire attached to galvanized steel cable
  - Prevents displacement and buckling of wires
- Used to increase radial force as device is expanded
Design Alternative 3: Air Balloon

- Inflatable bladder within device attached at end and mid-caps

- After device is expanded, bladder inflated with compressed air

- Prevents buckling of wires and adds to radial force of the device
# Design Matrix

<table>
<thead>
<tr>
<th>Parameters (weight)</th>
<th>Design 1: Mesh Cylinder</th>
<th>Design 2: 2-Sided Umbrella</th>
<th>Design 3: Inflated Air Bag</th>
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<tr>
<td>Fixation (30)</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>Radial Force (20)</td>
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<tr>
<td>Ease of Entry (20)</td>
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<td>4</td>
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<tr>
<td>Safety/Biocompatibility (15)</td>
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<tr>
<td>Feasibility/Fabrication (10)</td>
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<tr>
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<tr>
<td>Total (100)</td>
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<td><strong>61</strong></td>
<td><strong>62</strong></td>
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Design Selection:

Mesh Cylinder Design

- Easiest to fabricate
- No biocompatibility concerns – all metal
- Longest canal-device interface due to surface area increase
- Made with surgical grade stainless steel or tantalum mesh – biocompatible
Future Work

• Obtain previous semester’s device
• Order materials for mesh cylinder
• Fabricate mesh cylinder prototype
• Integrate prototype with existing device
• Test integrated device
  • MTS testing of integrated device
  • Static friction testing of integrated device
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Questions
References


